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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,073	12/21/2001	Jean L. Lalanne	146.1375	4668
20311	7590	03/18/2004	EXAMINER	
MUSERLIAN AND LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/018,073

Applicant(s)

FAUVEAU ETAL

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-16, 19 and 20 are pending.

Applicants' amendment filed December 4, 2003 is acknowledged. Applicant's response has been fully considered. Claims 1-16, 19 and 20 have been amended. Therefore, claims 1-16, 19 and 20 are examined.

### **Objection Withdrawn**

2. The previous objection of claims 1-16, 19 and 20 is withdrawn in view of applicant's amendment to the claim in the amendment filed December 4, 2003.

### **Rejection Withdrawn**

### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 19 and 20 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 11 in the amendment filed December 4, 2003.
4. The previous rejection of claims 12 and 13 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 10-11 in the amendment filed December 4, 2003.

### ***Claim Objections***

5. Claim 1 is objected to because there is no comma (,) or "semicolon (;) at the end of the description for "R<sub>1</sub> and R<sub>2</sub>" or "R<sub>3</sub>".

### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-16, 19 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 8-11, 14 and 17-20 of U. S. Patent 6,677,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-14 in the instant application disclose a compound of formula I consisting of all possible isomeric forms, where R<sub>1</sub> is hydrogen or methyl and R<sub>2</sub> is a cyclohexyl group substituted with an amine, or certain amine- or hydroxy-containing alkyl group, or R<sub>1</sub> and R<sub>2</sub> together with the nitrogen to which they are attached form a ring of 3, 4 or 5 carbons optionally substituted by an amine, a process for the preparation of a compound of formula I, an antifungal composition comprising a specific compound of formula I, and a method of treating fungal infection in warm-blooded animals comprising administering a specific compound of formula I. This is obvious in view of claims 1, 2, 4, 5, 8-11, 14 and 17-20 in the patent which disclose a compound of formula I consisting of all possible stereoisomeric forms, where R<sub>1</sub> and R<sub>2</sub> are individually selected from the group consisting of hydrogen, OH, alkyl and a cycloalkyl of up to 8 carbon atoms optionally interrupted with oxygen and optionally substituted with halogen, OH and N(-a) (-b), where a and b are individually hydrogen or alkyl of up to 8 carbon atoms or taken together with the nitrogen form a heterocyclic optionally

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containing one or several additional heteroatoms, a process for the preparation of a compound of formula I, an antifungal composition comprising a compound of formula I, and a method of inhibiting proliferation of fungi in warm-blooded animals comprising administering a compound of formula I. The claim of the instant application and the claims of the patent are directed to a compound of formula I consisting of all possible isomeric forms, a process for the preparation of a compound of formula I, an antifungal composition comprising a specific compound of formula I, and a method of treating fungal infection in warm-blooded animals comprising administering a specific compound of formula I. Thus, claims 1-16, 19 and 20 in present application and claims 1, 2, 4, 5, 8-11, 14 and 17-20 in the patent are obvious variations of a compound of formula I consisting of all possible isomeric forms, a process for the preparation of a compound of formula I, an antifungal composition comprising a specific compound of formula I, and a method of treating fungal infection in warm-blooded animals comprising administering a specific compound of formula I.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1-16, 19 and 20 are indefinite because of the use of the term "all possible isomeric forms and their mixtures", " $-(CH_2) B-C \equiv N$ ", " $-CH_2 \equiv N$ " or "and/or". The term "all possible isomeric forms and their mixtures", " $-(CH_2) B-C \equiv N$ ", " $-CH_2 \equiv N$ " or "and/or" renders

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the claim indefinite, it is unclear what isomers are intended as the possible isomeric forms, what isomers and how much of each isomer are included in the mixture, what group is as to “-(CH<sub>2</sub>) B-C≡N” or “-CH<sub>2</sub>≡N” since the claim does not define “B” and the carbon in “-CH<sub>2</sub>≡N” has five bonds, and whether the limitation after “and/or” is included or not, and if included is to be read as an alternative “or” or the conjunctive “and”. Note that Markush groups must be closed and “and their mixtures” is open language in regard to the number of components and amounts of each in the mixtures which are defined. Claims 2-16, 19 and 20 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the term “and/or” has been deleted from claim 1, however, claim 16 still contains this term, thus, rejection remains for claim 16. The issue regarding rejection of the term “all possible isomeric forms and their mixtures” has not been addressed in the response.

9. Claim 16 is indefinite because of the use of the term “functionalization agent” or “a separation agent of the different isomers”. The term “amine functionalization agent” or “a separation agent of the different isomers” renders the claim indefinite, it is unclear what compound is intended as amine functionalization agent; and what agent is used for separation of different isomers.

In response, applicant has amended the claim to delete the term “derivative”, thus the rejection is withdrawn. However, the issue regarding rejection of the term “functionalization agent” or “a separation agent of the different isomers” has not been addressed in the response.

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10. Claim 20 is indefinite because the claim lacks essential steps in the method of treating fungal infection. The omitted step is outcome of the treatment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-16, 19 and 20 are rejected under 35 U.S.C. 102(e) as anticipated by Courtin *et al.* (U. S. Patent 6,677,429, priority date December 9, 1998).

Courtin *et al.* teach a compound of formula I consisting of all possible isomeric forms, where R<sub>1</sub> and R<sub>2</sub> are individually selected from the group consisting of hydrogen, OH, alkyl and a cycloalkyl of up to 8 carbon atoms optionally interrupted with oxygen and optionally substituted with halogen, OH and N(-a) (-b), where a and b are individually hydrogen or alkyl of up to 8 carbon atoms or taken together with the nitrogen form a heterocyclic optionally containing one or several additional heteroatoms (column 1, lines 10-54; columns 3, 4; claims 1-

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15), a process for the preparation of a compound of formula I by reacting of a compound of formula II with an amine to introduce N(-R<sub>1</sub>) (-R<sub>2</sub>) group (column 6, line 24-column 7, line 3; claim 16). The reference also teaches the compound of formula I has significant anti-fungal activity and can be used to prepare an anti-fungal composition and as medicines in man or animal to fight against fungal infections (column 5, line 32-column 6, line 21; column 16, lines 34-62; claims 19 and 20).

### *Conclusions*

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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March 10, 2004



ROBERT A. WAX  
PRIMARY EXAMINER